

June 8, 2004

Office of Nutritional Products, Labeling and Dietary Supplements (HFS-800)
Center for Food Safety and Applied Nutrition Food and Drug Administration
Department of Health and Human Services 5100 Paint Branch Parkway, Building CPK1
College Park, Maryland 20740-3835

RE: Petition for Nutrient Content Claims for Carbohydrates Submitted by Unilever United States, Inc., April 16, 2004

To Whom It May Concern:

On April 16, 2004, Unilever United States, Inc. submitted to FDA a petition to permit the use of nutrient content claims for the carbohydrate content of food. This letter provides additional information relevant to FDA's evaluation of our petition.

On May 26-27, 2004, the Dietary Guidelines Advisory Committee, a joint committee of the Department of Health and Human Services and Department of Agriculture, met to discuss its recommendations for the 2005 edition of *Dietary Guidelines for Americans*.

According to press reports, the Committee said that individuals should consume about 14 grams of dietary fiber for every 1,000 calories eaten – about 28 grams of fiber a day for most women and about 35 grams for most men. The current DRV for fiber is 25 grams; therefore the Committee's reported statement suggests a need to significantly increase dietary fiber intake among the U.S. population.

Our petition requests the adoption of "free," "low," and "reduced" carbohydrate claims that are based on the level of caloric carbohydrates in a food (principally starches and sugars). Dietary fiber and other non-caloric carbohydrates would *not* be counted for purposes of determining whether a food is "free," "low," or "reduced" in carbohydrate. As a result, when consumers select a "free," "low," or "reduced" carbohydrate food, they would only be restricting their intake of caloric carbohydrates, not their intake of dietary fiber and other non-caloric carbohydrates. This approach is intended to help consumers

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Washington Post: Diet Panel Emphasizes More Fiber, Less Fat: Federal Committee Prepares Recommendations. May 28, 2004 (page A03).

Food and Drug Administration (HFS-800) June 8, 2004 Page 2

construct a healthy diet, particularly with respect to reducing the risk of overweight and obesity.

Importantly, our petition is consistent with the goal of increasing the intake of dietary fiber among the U.S. population, because the claims proposed by our petition would not encourage consumers to restrict dietary fiber intake. In contrast, if FDA were to adopt claims that require foods to be "free," "low," or "reduced" in dietary fiber as well as other carbohydrates, such claims would encourage consumers to inappropriately restrict their dietary fiber intake.

In addition, our petition requests the adoption of "good source" and "excellent source" claims for carbohydrates, and proposes that foods labeled with these claims must provide a good source of fiber. For this reason as well, our proposed claims would encourage increased fiber consumption.

Accordingly, the reported statements of the Dietary Guidelines Advisory Committee regarding the need for increased dietary fiber intake provide further support for the approach taken by our petition. At this time, these statements are not final or official, and press reports provide the only documentation of them. We understand that the Committee will meet again on August 10-11, 2004 and thereafter issue a report to the government. We will continue to monitor the statements of the Committee and provide additional information relevant to our petition as it becomes available.

Thank you for considering this information as you evaluate our petition.

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Deputy General Counsel -Marketing and Regulatory

cc: Kathleen Ellwood Shellee Anderson ONPLDS/DNPL